

DETAILED ACTION

Status of Claims

1. The following Office action in response to communications received September 8, 2011. Claim 1 has been amended. Claims 10-11 have been canceled. Therefore, claims 1-9 and 12-20 are pending and addressed below.
2. Applicant's amendments to the claims are not sufficient to overcome the 35 USC § 103(a) rejections set forth in the previous office action dated June 24, 2010.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on September 8, 2011 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 and 10-20 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Sabol et al. (US 2004/0122719) in view of Urquhart et al. (US 2004/0073454)

CLAIM 1.

Sabol et al. teaches a method for determining a degree of compliance with a performance specification assigned to a medical working practice, the method comprising:

- recording and storing, by a data-processing device, data correlated with the medical working practice; (see at least Paragraph 0008)

- storing, by a test system, test criteria for the data, the test criteria correlated with the performance specification, the performance specification being one of specifications or instructions of a research project, standard operating procedures (see at least Paragraph 0075; [protocol]) for medical procedures or treatments, inclusion and exclusion criteria for a clinical study, instructions to a patient or doctor, times or durations for physical activities and examination methods to be complied with; reading, via the test system, the data stored in the data-processing device; As stated in Paragraph [0019] of Applicants Summary, the degree of compliance may moreover lead to a simple Yes/No decision, i.e. compliance or noncompliance with the performance specification. (see at least Paragraph 0332 wherein, provided are structured video and/or audio recordings of questions and answers; Figures 1-31 Paragraph 0004 and 0008)

Examiner notes that the system of Sabol teaches a system that *stores data* (i.e. instructions or protocols) . For example, modality-specific knowledge base data may include factors such as system settings, preferred settings for specific patients or populations, **routines and protocols**, data interpretation algorithms based upon the specific modality, and so forth. The knowledge bases are generally available to clinicians 6 and, *where desired, may be based upon input from such clinicians*. Input can be the test criteria correlated with the performance specification.

Sabol et al. does not explicitly teach a method for evaluating, via the test system, the data with the aid of the test criteria and determining the degree of compliance with the performance specification. It would have been obvious to one of ordinary skill in the art at the time of the

invention to expand the method of Sabol et al. to include event monitoring devices that are helpful in reporting to the physician the dosing history of a patient, from which the patient's degree of compliance with the prescribed drug regimen can be determined (see at least Paragraph 0004) as taught by Urquhart et al. One of ordinary skill in the art at the time of the invention would have been motivated to expand the process of Sabol et al. in this way since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

CLAIM 2.

Sabol et al. teaches a method as claimed in claim 1, wherein:

- clinical data are collected as the medical working practice, the collection process being assigned a collection protocol (Acquisition techniques) as the performance specification (see at least Figures 1-31 Paragraph 0004 and 0008).

CLAIM 3.

Sabol et al. teaches a method as claimed in claim 2, wherein:

- a measurement value for a clinical study is collected from a patient as the medical working practice, and the test system sends the measurement value as a valid measurement value to a study database if the collection protocol is complied with (see at least Figures 1-31 Paragraph 0004 and 0008).

CLAIM 4.

Sabol et al. teaches a method as claimed in claim 1, wherein:

- a knowledge-based system is used as the test system, and the performance specification is stored in the form of a rule set in the knowledge-based system (see at least Paragraph 0075 Figures 5[62-74]; Paragraph 0306).

CLAIM 5.

Sabol et al. teaches a method as claimed in claim 4, wherein:

- the performance specification is stored as a module in the rule set (see at least Paragraph 0075 Figures 5[62-74]; Paragraph 0306).

CLAIM 6.

Sabol et al. teaches a method as claimed in claim 1, wherein:

- the method is carried out automatically after each medical working practice (see at least Paragraph 0288)

CLAIM 7.

Sabol et al. teaches a method as claimed in claim 1, wherein:

- if the performance specification is not complied with, a decision is made as to whether it is possible to repeat the working practice and, if so, repetition is requested; and if repetition is possible, a corresponding repetition request is made (see at least Paragraph 0294).

Sabol et al. does not expressly teach the specific data recited in claims 7. These differences are only found in the non-functional descriptive material and are not functionally involved in the manipulative steps of the invention nor do they alter the recited structural elements; therefore, such differences do not effectively serve to patentably distinguish the claimed invention over the prior art. The manipulative steps of the invention would be performed the same regardless of the specific data. Further, the structural elements remain the same regardless of the specific data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability as the claimed invention fails to present a new and unobvious functional relationship between the descriptive material and the substrate, *see In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed.

Cir. 1994)); In re Ngai, 367 F.3d 1336, 1336, 70 USPQ2d 1862, 1863-64 (Fed. Cir. 2004); MPEP § 2106.

CLAIM 10.

Sabol et al. teaches a method as claimed in claim 8, wherein:

- the performance specification is stored as a module in the rule set.
- (see at least Paragraph 0020)

Examiner notes that module has not been explicitly explained in applicants Detailed Specification. Therefore, using the broadest reasonable interpretation module is considered to be a program or software which is not patentable under **35 USC § 101**. Refer to MPEP.

CLAIM 11.

Sabol et al. teaches a method as claimed in claim 9, wherein:

- the performance specification is stored as a module in the rule set.
- (see at least Paragraph 0020)

Examiner notes that module has not been explicitly explained in applicants Detailed Specification. Therefore, using the broadest reasonable interpretation module is considered to be a program or software which is not patentable under *35 USC § 101*. Refer to MPEP.

CLAIMS 12-15.

Sabol et al. teaches a method as claimed in claims (2-5) wherein:

- the method is carried out automatically after each medical working practice.

CLAIMS 16 – 20.

Claim 16-20 is directed to a method for determining a degree of compliance with a performance specification assigned to a medical working practice. Claim 16-20 recites the same or similar limitations as those addressed above for Claim 7. Claim 16-20 is therefore rejected for the same reasons as set forth above for Claim 7 respectively.

Claims 8-9 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Sabol et al. (US 2004/0122719) in view of Urquhart et al. (US 2004/0073454) further in view of Miller et al. (US 5,446,653).

CLAIMS 8 & 9.

Sabol et al. further teach(s) a method as claimed in claim 2 & 3, wherein:

- a knowledge-based system is used as the test system (see at least Figure 10-14[136])

Sabol et al. does not explicitly teach a method as in claims 2 & 3 wherein the performance specification is stored in the form of a rule set in the knowledge-based system. It would have been obvious to one of ordinary skill in the art at the time of the invention to expand the method of Sabol et al. to include documents that are automatically generated by assembling a plurality of clauses selected from a library of clauses stored in a computer system. A rule set is assigned to each of the clauses. Each rule set provides at least one rule that must be satisfied in order to include the clause associated therewith in a document (see at least Abstract) as taught by Miller et al. One of ordinary skill in the art at the time of the invention would have been motivated to expand the process of Sabol et al. in this way since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Response to Arguments

Applicant's arguments filed September 8, 2011 have been fully considered but they are not persuasive. In the remarks applicant argues (1) Sabol fails to disclose "test criteria... correlated with performance specification."

In response to argument (1), Examiner respectfully disagrees. Examiner notes that the system of Sabol teaches a system that *stores data* (i.e. instructions or protocols, criterion, etc.) . For example, modality-specific knowledge base data may include factors such as system settings, preferred settings for specific patients or populations, **routines and protocols**, data interpretation algorithms based upon the specific modality, and so forth. The knowledge bases are generally available to clinicians 6 and, *where desired, may be based upon **input** from such clinicians*. Input can be the test criteria correlated with the performance specification. Nonetheless, it's data that is input and stored.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Aryev et al. (US 6581012); Huggard et al. (US 2004/0243439).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EDWARD WINSTON III whose telephone number is (571) 270-7780. The examiner can normally be reached on MONDAY-THURDAY; 11:00AM-8:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

Official replies to this Office action may now be submitted electronically by registered users of the EFS-Web system. Information on EFS-Web tools is available on the Internet at: <http://www.uspto.gov/patents/process/file/efs/guidance/index.jsp>. An EFS-Web Quick-Start Guide is available at: <http://www.uspto.gov/ebc/portal/efs/quick-start.pdf>.

Alternatively, official replies to this Office action may still be submitted by any *one* of fax, mail, or hand delivery. **Faxed replies should be directed to the central fax at (571) 273-8300.** Mailed replies should be addressed to “Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.” Hand delivered replies should be delivered to the “Customer Service Window, Randolph Building, 401 Dulany Street, Alexandria, VA 22314.”

/E. W./
Examiner, Art Unit 3686
25 October 2011

/Gerald J. O’Connor/
Supervisory Patent Examiner
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